

EXHIBIT 3



FDA Approved Drug Products

Start Over[FAQ](#) | [Instructions](#) | [Glossary](#) | [Contact Us](#) | [CDER Home](#)

Drug Details

Drug Name(s) ARAVA (Brand Name Drug)
FDA Application No. (NDA) 020905
Active Ingredient(s) LEFLUNOMIDE
Company SANOFI AVENTIS US
Original Approval or Tentative Approval Date September 10, 1998
Chemical Type 1 New molecular entity (NME)
Review Classification P Priority review drug

- [Therapeutic Equivalents](#)
- [Approval History, Letters, Reviews, and Related Documents](#)
- [Label Information](#)
- [Consumer Information Sheet](#)

Products on Application (NDA) #020905

Click on a column header to re-sort the table:

<u>Drug Name</u>	<u>Active Ingredients</u>	<u>Strength</u>	<u>Dosage Form/Route</u>	<u>Marketing Status</u>	<u>RLD</u>	<u>TE Code</u>
ARAVA	LEFLUNOMIDE	10MG	TABLET; ORAL	Prescription	No	AB
ARAVA	LEFLUNOMIDE	20MG	TABLET; ORAL	Prescription	Yes	AB
ARAVA	LEFLUNOMIDE	100MG	TABLET; ORAL	Prescription	Yes	None

[Back to Top](#) | [Back to Previous Page](#) | [Back to Drugs@FDA Home](#)

Disclaimer

[CDER Home Page](#) | [CDER Site Info](#) | [Contact CDER](#) | [What's New @ CDER](#)
[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [Privacy](#) | [Accessibility](#) | [HHS Home Page](#)

FDA/Center for Drug Evaluation and Research
Office of Training and Communications
Division of Information Services
Update Frequency: Daily